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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,473	09/07/2000	Jean-Francois Lucien Maisonneuve	B45069-1	1711

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EXAMINER
ZEMAN, ROBERT

ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/657,473	Applicant(s) MAISONNEUVE ET AL.	
	Examiner Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-9,12,13,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10,11,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group III in Paper No. 6 is acknowledged.

Since the searching of claims 1-5, 10-11 and 14 is required in order to properly examine claim 17, said claims are rejoined. Therefore, only claims 6-9, 12-13 and 15-16 have been withdrawn from consideration and claims 1-5, 10-11, 14 and 17 are currently under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Claim 17 is objected to because of the following informalities: preceding claims must be referred to in the alternative only.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1-5, 10-11, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccines comprising a major outer membrane protein (MOMP) from *Chlamydia trachomatis* serovars L2 and F and their use in methods of inducing heterotypic prophylaxis of infertility induced by *Chlamydia trachomatis* serovars L2 and F, does not reasonably provide enablement for vaccines comprising a major outer membrane protein (MOMP) from any other species/serovars of *Chlamydia* other than *Chlamydia trachomatis* serovars L2 and F. Additionally the specification does not reasonably provide enablement for the use of the aforementioned vaccines in methods of inducing heterotypic prophylaxis of infertility induced by any other species/serovars of *Chlamydia* other than *Chlamydia trachomatis* serovars

L2 and F. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The above rejected claims are drawn to prophylactic subunit vaccine compositions. To be a prophylactic vaccine, the vaccine must provide protective immunity, demonstrable by challenge experiments, in a reasonable model system. The specification, as filed, does not set forth that **all** the claimed compositions provide any sort of protective immunity in any model system that can be extrapolated to humans or higher mammals commensurate in scope with the claimed invention. The specification provides detailed methodology in the production and use of subunit vaccines, MOMPL2 and MOMPF. Said vaccines were derived from the major outer membrane proteins of *Chlamydia* trachomatis serovars L2 and F, respectively. The specification demonstrates that said vaccines provide heterotypic protection from infertility induced by *Chlamydia* trachomatis serovars F and L2. The specification is silent of the efficacy of MOMPL2 and MOMPF in providing heterotypic protection from infertility induced by any other *Chlamydia* species or *Chlamydia trachomatis* serovars other than F and L2 (see pages 19-39). The specification is equally silent on what MOMP subunit vaccines, if any, derived from other *Chlamydia* species would be effective in providing heterotypic protection from infertility induced by *Chlamydia* trachomatis serovars F and L2. While the skill in the art of bacteriology and immunology is high, to date, prediction of protective immunity for any given composition is quite unpredictable. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of protective immunity, the specification, as filed, is only enabling for vaccines derived from the major outer membrane proteins of *Chlamydia*

trachomatis serovars L2 and F and their use for providing provide heterotypic protection from infertility induced by *Chlamydia* trachomatis serovars F and L2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 10-11, 14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 10-11, 14 and 17 are drawn to a major outer membrane protein; however said claims do no set forth either the amino acid sequence of the claimed protein or the nucleic acid sequence of the DNA which encodes said protein, nor do the claims provide any structural properties, such as molecular weight, of the protein which would allow one to identify the protein without ambiguity.

Claim 1 is rendered vague and indefinite by the use of the term "TH1-like immune response". It is unclear what is meant by said term. To what degree is it similar to a TH1 immune response? How does it differ? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "D to K". It is unclear what serovars are included in the Markush group.

Claim 5 recites improper Markush language. Said claim recites "from the group **comprising**". Said language is open and therefore improper. Proper Markush language must be closed. Additionally, the ultimate member of said group should be preceded with the conjunction

"and" when using the preamble "from the group consisting of". Finally, it is unclear what is meant by "a combination of". Is QS21 a member of all possible combinations?

Claim 11 is rendered vague and indefinite by the use of the term "adapted for oral or intranasal administration. It is unclear what is meant by said claim. What type of "adaptation" is being claimed? What active steps are required to make such an "adaptation" or what additional physical properties are being claimed? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 17 is rendered vague and indefinite by the use of the phrase "a vaccine composition of claims 1-4". It is unclear whether said vaccine is to be selected from those recited in claims 1-4 or whether said vaccine composition comprises the vaccines recited in claims 1-4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (Investigative Ophthalmology and Visual Science, Vol. 29, No. 12, pages 1847-1853, 1988 -- IDS-4).

Taylor et al. disclose the use of MOMP from *Chlamydia* in conjunction an adjuvant (e.g. cholera toxin) to immunize animals against chlamydial infection and the effects of said infection

(see page 1848). Though Taylor does not explicitly deal with the use of MOMPs to prevent or reduce infertility caused by *Chlamydia* (claim 17) Taylor still anticipates said limitation since the reduction in infertility is an inherent property of the MOMP composition and one would derive all the benefits of said composition regardless of the initial motivation for using said composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 10-11, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (Investigative Ophthalmology and Visual Science, Vol. 29, No. 12, pages

1847-1853, 1988 -- IDS-4) in view of Ward (Journal of Infection, Vol. 25, Supplement I, pages 11-26, 1992).

Taylor et al. disclose the use of MOMP from *Chlamydia* in conjunction with an adjuvant (i.e. cholera toxin) to immunize animals against chlamydial infection and the effects of said infection (see page 1848). Taylor et al. differ from the claimed invention in that they do not disclose the use of recombinant proteins or specifically recite the use of MOMPs from different serovars. Ward teaches that the only protective antigen that has been unambiguously identified, with regard to chlamydial vaccine development, is the chlamydial major outer membrane protein, MOMP (see entire reference, for example page 17). Ward further discloses the use of MOMPs from *Chlamydia* serovars L1 and L2 as a protective antigen. Therefore it would have been obvious to one of skill in the art to use the MOMPs from various serovars, singly and in combination, in vaccine compositions. It would have been equally obvious for one of skill in the art to use various adjuvants to maximize the immune response to the MOMP antigens. One would have had a high expectation of success since, as disclosed by Ward, MOMPs are protective antigens.

Claims 1-5, 10-11, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (Journal of Infection, Vol. 25, Supplement I, pages 11-26, 1992) in view of. Prieels et al. (WO 94/00153)

Ward teaches that the only protective antigen that has been unambiguously identified, with regard to chlamydial vaccine development, is the chlamydial major outer membrane protein, MOMP (see entire reference, for example page 17). Ward further discloses the use of

MOMPs from *Chlamydia* serovars L1 and L2 as a protective antigen. Prieels et al. disclose a vaccine formulation comprising an antigen or antigenic composition capable of eliciting an immune response against a human or animal pathogen, for example an antigen or antigenic composition derived from a bacterial pathogen such as *Chlamydia* (see entire reference, for example first paragraph on page 5), in conjunction with QS21 And 3DMPL. Therefore it would have been obvious to one of skill in the art to use the MOMPs from various serovars, singly and in combination, in vaccine compositions. It would have been equally obvious for one of skill in the art to use various adjuvants to maximize the immune response to the MOMP antigens. One would have had a high expectation of success since, as disclosed by Ward, MOMPs are protective antigens.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
May 6, 2002